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Matrix Surgical USA
Traditional 510(k) - OmniPore® Surgical Implants JUL 3 1 2013

510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements under 21 CFR 807.92.

Submitted By: Matrix Surgical USA
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Contact Person: Julie Stephens, President/Consultant
Regulatory Resources Group, Inc.

Date Submitted: July 26, 2013

Device Name and Classification:

Trade/Proprietary Name:	OmniPore® Surgical Implants
Common Name:	Porous HD Polyethylene (HDPE) Implants
Classification Name:	Material, porous polymer, for maxillofacial reconstruction
Class:	II
Regulation:	21 CFR 878.3500
Product Code:	KKY

Legally Marketed Predicate Devices:

POREX Surgical Inc. (now owned by Stryker® Craniomaxillofacial) - MEDPOR® Surgical Implant Material: Preformed Cranial and Facial Implants - 510(k) # K922489

Device Description:

The OmniPore® Surgical Implants are marketed as single use sterile implants with various shapes and sizes for different areas of the craniofacial skeleton. The applications include non-load bearing augmentation and/or reconstruction of the craniofacial skeleton.

The raw material used for the OmniPore® Surgical Implants is high-density polyethylene when molded into the implants becomes a porous high-density polyethylene. Polyethylene has a long history of use in surgical implantable products. The interconnecting open pore structure of the OmniPore® Surgical Implants allow for tissue in growth. Additionally, Animal histology has shown fibrovascular ingowth occurs into the open pore structure of OmniPore Surgical Implants. The material used to manufacture the OmniPore® Surgical Implants has been utilized in reconstruction and soft tissue repair for many years. There is a long history of the use of porous polyethylene implants for enucleation and evisceration, as well as for many applications in craniofacial reconstruction and augmentation, with a history of safety and performance.

The implants are single use and provided sterile by ethylene oxide (EO) terminal sterilization.

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Matrix Surgical USA
Traditional 510(k) - OmniPore® Surgical Implants

510(k) SUMMARY

Indications for Use:

OmniPore® Surgical Implants in block, sheet, and anatomical shapes are intended for non-weight bearing applications of craniofacial reconstruction/cosmetic surgery and repair of craniofacial trauma. OmniPore Surgical Implants are also intended for the augmentation or restoration of contour in the craniomaxillofacial skeleton.

Similarities and Differences to the Predicate Devices:

Similarities

The same raw materials, manufacturing processes, packaging materials, performance standards, and the same indications for use are used in the OmniPore and the predicate devices.

Differences

There are slight differences in the OmniPore when compared against the predicates specific to manufacturing facility locations.

Summary of Testing:

The OmniPore Surgical Implants were tested to the biocompatibility standards to demonstrate that they are substantially equivalent materials as the predicate devices in regards to Cytotoxicity, ISO Systemic Toxicity, ISO Intracutaneous Study, USP Pyrogen Study, and ISO Muscle Implantation Study. The OmniPore Surgical Implants completed sterilization validation to validate that they are sterile devices for implantation as equivalent to the predicate devices. The OmniPore Surgical Implants completed mechanical testing specific to impact testing, purity testing per USP, and porosity testing.

Substantial Equivalence Conclusions:

The OmniPore® Surgical Implants have the same intended use and indications for use, and the same technological characteristics and principles of operation as the predicate devices. The minor differences do not raise any issues of safety or effectiveness. Testing results support the determination of substantial equivalence with the results demonstrating that the OmniPore Surgical Implants have equivalent results as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 31, 2013

Matrix Surgical USA
% Ms. Julie Stephens
President/Consultant
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

Re: K123908
Trade/Device Name: OmniPore® Surgical Implants
Regulation Number: 21 CFR 878.3500
Regulation Name: Polytetrafluoroethylene with carbon fibers composite implant material
Regulatory Class: Class II
Product Code: KKY
Dated: July 1, 2013
Received: July 1, 2013

Dear Ms. Stephens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123908

Device Name: OmniPore® Surgical Implants and Accessories

Indications for Use:

OmniPore® Surgical Implants in block, sheet, and anatomical shapes are intended for non-weight bearing applications of craniofacial reconstruction/cosmetic surgery and repair of craniofacial trauma. OmniPore Surgical Implants are also intended for the augmentation or restoration of contour in the craniomaxillofacial skeleton.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123908